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# SWalker: a robotic platform to aid rehabilitation following hip fracture

**Submission date**
19/02/2021

**Recruitment status**
No longer recruiting

**Registration date**
25/02/2021

**Overall study status**
Completed

**Last Edited**
23/02/2021

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

**Plain English summary of protocol**
Background and study aims
Hip fracture is one of the most common traumas associated with falls in the elderly, severely affecting the patient's mobility and independence. The treatment involves hospitalization and prolonged rehabilitation periods with high costs which are associated with an increased mortality rate due to health complications. In recent years, the use of robotic applications has proven to be effective in gait rehabilitation, especially for neurological disorders. However, there is a lack of research in robotic rehabilitation focused on hip fracture of elderly people. This paper presents the design and validation of a novel robotic platform for hip rehabilitation called SWalker aimed at improving the rehabilitation of this condition.

Who can participate?
Patients who, after recently having undergone a hip fracture surgery, needed subsequent rehabilitation to walk again.

What does the study involve?
Participants were allocated to receive treatment using the SWalker or treatment as usual.

What are the possible benefits and risks of participating?
Benefits: The fundamental objective is to reduce patient mortality and recover the functional situation prior to hip fracture in elderly people who have suffered this pathology, and also that these achievements can be reached in the shortest possible time and at the lowest possible socio-economic cost, establishing the necessary strategies so that these benefits are maintained in the medium and long term.
Risks: No risks are foreseen.

Where is the study run from?
Albertia Servicios Sociosanitarios S.A. nursing homes (Spain)

When is the study starting and how long is it expected to run for?
March 2018 to April 2020

Who is funding the study?
1. Centro para el Desarrollo Tecnológico Industrial (CDTI) of the Ministry of Science and Innovation, Government of Spain
2. EDER/ Ministry of Science and Innovation/AEI) (Spain)

Who is the main contact?
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# Contact information

### Type(s)
Public

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
SWALKERS17

# Study information

### Scientific Title
SWalker: a robotic platform for hip fracture rehabilitation

### Acronym

SWalker

## Study objectives
Hip fracture is one of the most common traumas associated with falls in the elderly, severely affecting the patient's mobility and independence. The treatment involves hospitalization and prolonged rehabilitation periods with high costs which are associated with an increased mortality rate due to health complications. In recent years, the use of robotic applications has proven to be effective in gait rehabilitation, especially for neurological disorders. However, there is a lack of research in robotic rehabilitation focused on the hip fracture of elderly people. This study presents the validation of a novel robotic platform for hip rehabilitation called SWalker aimed at improving the rehabilitation of this condition in comparison with conventional rehabilitation.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 15/01/2019, Fundación Jiménez Díaz Clinical Research Ethics Committee (Avda. de los Reyes Católicos, 2, 28040-Madrid, Spain; +34 915443720; ceic@fjd.es), ref: CPMP/ICH/135/95

## Study design
Interventional non-randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

## Health condition(s) or problem(s) studied
Recovery from hip fracture in elderly people

## Interventions
The performance of the SWalker platform was assessed at Albertia Servicios Sociosanitarios S.A. nursing homes.
Clinical validation was conducted with hip fracture patients.

The control group consisted of patients who followed conventional therapy, while the intervention group consisted of patients rehabilitated using SWalker. Allocation to groups was according to the choice of the participants. All patients had the possibility to use SWalker treatment.

Physiological parameters, and functional assessment scales such as FAC and Tinetti were collected at the beginning and at the end of the intervention. Gait recovery and rehabilitation process indicators were also gathered.

The total duration of the clinical validation was 15 months.
For each patient, the total duration of treatment was between 1 week and 1 month with the robotic platform.
For those patients who received conventional rehabilitation, treatment duration was up to 6 months in the most severe case. Patient follow-up was conducted in parallel with the clinical trials.

### Intervention Type
Device

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
SWalker

### Primary outcome measure
1. Effectiveness of the device in injury recovery was measured with the variables "Number of physiotherapy sessions" and "Injury recovery time", which were quantified for each patient after the end of treatment (recovery defined as: no technical assistance or support staff needed to move around)
2. Degree of gait recovery measured by visual inspection by the clinical staff, assessing at the end of treatment whether the patient had fully recovered independent walking to perform their daily functional tasks (no technical assistance or support staff needed to move around), partially (requiring technical assistance such as a conventional walker, wheelchair, etc.) or not recovered walking at all

### Secondary outcome measures
1. The quality of the patient's gait was measured with the Barthel index, Functional Ambulation Category (FAC), and Tinetti scale at the beginning and at the end of the treatment
2. The patients' nutritional and cognitive state was measured with the Mini Nutritional Assessment (MNA) and the Mini Examen Cognoscitivo (MEC) at the beginning and at the end of the treatment

### Overall study start date
01/03/2018

### Completion date
15/04/2020

## Eligibility

### Key inclusion criteria
1. Patients who, after recently having undergone a hip fracture surgery, needed subsequent rehabilitation to restore autonomous ambulation
2. Not received any other type of HF rehabilitation therapy

**Participant type(s)**
Patient

**Age group**
Senior

**Sex**
Both

**Target number of participants**
34

**Total final enrolment**
34

**Key exclusion criteria**
Does not meet inclusion criteria

**Date of first enrolment**
15/01/2019

**Date of final enrolment**
01/11/2019

# Locations

**Countries of recruitment**
Spain

**Study participating centre**
**Albertia Servicios Sociosanitarios S.A.**
Las Rozas De Madrid
Madrid
Spain
28222

# Sponsor information

**Organisation**
Albertia Servicios Sociosanitarios S.A.

**Sponsor details**
Las Rozas De Madrid
Madrid

Spain
28222
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### Sponsor type
Hospital/treatment centre

## Funder(s)

### Funder type
Government

### Funder Name
Centro para el Desarrollo Tecnológico Industrial (CDTI)

### Funder Name
Ministry of Science and Innovation (Government of Spain)

## Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

### Intention to publish date
01/04/2021

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (https://zenodo.org/record/4549307#.YC6fPWhKhPZ)

### IPD sharing plan summary
Stored in repository